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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,271	03/08/2005	Alan Crossman	0206.MO.05	3503

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EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
10/07/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efspatents@sbiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/527,271	CROSSMAN ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-37,39-45 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/3/10; 6/15/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on August 3, 2010. Claim(s) 26-37, 39-45 and 51are examined herein.

Response to Arguments

Applicant's arguments with respect to 103(a) rejection of claims 26-34, 36, 37, and 39-45 as being unpatentable over Leventer (US Patent No. 6,649,607 B2) in view of Chenard et al. (EP 0900568 A2) have been fully considered but are not persuasive.

Applicant's arguments with respect to 103(a) rejection of claim 35 as being unpatentable over Leventer (US Patent No. 6,649,607 B2) in view of Chenard et al. (EP 0900568 A2) as applied to claims 26-34, 36, 37, and 39-45 above in further view of http://web.archive.org/web/20000815082545/neurologychannel.com/parkinsonsdisease/index.shtml (referred to as "PD website" heretofore) have been fully considered but are not persuasive.

Applicant argues:

> "because the majority of the studies described in Leventer's Background section indicated a lack of anti-convulsant activity on the part of tofisopam, the person of ordinary skill in the art would be taught from employing tofisopam in such treatment. This teaching away is not reversed by the data provided in Leventer's examples. In fact, racemic tofisopam was used as a comparison point to illustrate the significant anti-convulsant effect of S-tofisopam. While racemic tofisopam did exhibit some intrinsic anti-convulsant activity against picrotoxin-induced seizures in male NSA mice, the

> S-tofisopam displayed significantly greater anti-convulsant activity than the racemate compound. Indeed, throughout the entire reference, Leventer consistently promotes the use of S- tofisopam substantially free of R-tofisopam."

With respect to this argument, Examiner respectfully notes that as claimed, the compounds of formula I or more specifically tofisopam are a racemic mixture and do not specify one optical isomer over another. Therefore, Applicant's arguments are not commensurate in scope of the claimed invention.

Applicant further contends:

> "The instant claim is directed to a method of treating dyskinesia, wherein the dyskinesia is manifest as chorea or dystonia. The Examiner focuses on myoclonic jerks. Myoclonus describes a medical sign and may develop in response to infection, head or spinal cord injury, stroke, brain tumor, kidney or liver failure, lipid storage disease, chemical or drug poisoning, as a side effect of certain drugs, or in response to other disorders. It can occur by itself, but it is most often one of a number of symptoms associated with a wide variety of disorders. Chorea and dystonia are distinct in neurological origin from myoclonus. They are also different phenomenologically, and they respond differently to pharmacological agents."

These arguments are not persuasive. The definition of dyskinesia is defined as "excessive abnormal movements that are involuntary." Further, the different categories of dyskinesia are defined as including chorea, dystonia, myoclonus, tremor, etc (according to the website "answers.com"). Thus, because Leventer teaches that the administration of tofisopam treats convulsions and/or seizures including myoclonic jerks, it would be obvious to one of ordinary skill in the art to try, with a reasonable degree of success, to administer said drug to treat dyskinesia in view of Chenard's disclosure,

which teaches dyskinesia is as “excessive abnormal movements that are involuntary” including chorea, tremor, dystonia, myoclonus, and tic.

Furthermore Applicant argues:

> “Indeed, there is no enabling teaching in Chenard that compounds outside those in groups (A), (B), (C), (D), (E), and (F) are useful in the treatment of dyskinesia associated with dopamine agonist therapy. In this light, Applicant notes that, although the number of compounds speculated by Chenard for use in dyskinesia treatment is substantially large, the list of compounds does not include the compounds described in U.S. Patent Application No. 10/527,271, for example, tofisopam. Furthermore, the compounds listed in Chenard have significant structural differences from the compounds of the present application.
>
> It is further noted that, even assuming the Examiner's arguments and interpretation of the art are proper, Applicant still does not believe claim 26 to be obvious in light of Leventer and Chenard. The Examiner' s argument relies on myoclonic jerks being recognized by one of skill in the art as being symptomatic of dyskinesia, i.e., if a compound treats myoclonic jerks, it should treat dyskinesia (manifest as chorea or dystonia) "regardless of whether the dyskinesia results from the actual symptoms of a disease...or whether the dyskinesia is a side effect observed upon administration of an agent used to treat a particular disease..." However, because myoclonic jerks constitute a ubiquitous sign of numerous disorders, as iterated above, an ordinarily skilled artisan would understand, in fact, expect, that the number of compounds that could affect myoclonic jerks associated with so many disease states or disorders would be extensive to the point of requiring undue experimentation to test each and every one of them.”

Examiner is aware that the compounds taught in Chenard are structurally different than those of the instant invention, however, it is respectfully noted that the Chenard reference is employed to set forth on record the definition of dyskinesia and the various abnormal or uncontrollable movements associated therewith. Applicant

argues that myoclonic jerks constitute a ubiquitous sign of numerous disorders and given the large number of unrelated compounds taught by Chenard would require undue experimentation. It is noted that, Leventer teaches that S-tofisopam can be administered alone or in combination with one or more other anti-convulsant agents to treat convulsions or seizures including myoclonic jerks (i.e., clonic activity), therefore the fact that Chenard teaches a larger number of compounds than the instant application is not the point of contention. The fact that the specific compound, tofisopam, is taught by Leventer to be useful in treating myoclonic jerks would motivate one of ordinary skill in the art to at least try, with a reasonable degree of success, to also treat dyskinesia based on reasons of record.

Therefore, it is Examiner's opinion that based on the foregoing arguments and rejections made of record, the instant claims are deemed unpatentable over the cited art.

The 103(a) rejection is hereby maintained and modified as necessitated by amendment in the Office action below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26-34, 36, 37, 39-45 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leventer (US Patent No. 6,649,607 B2) in view of Chenard et al. (EP 0900568 A2).

Leventer teaches the administration of S-tofisopam for the treatment of convulsions or seizures selected from Parkinson's disease, other neurodegenerative diseases including Huntington's disease, schizophrenia, tics (e.g., Tourette's syndrome), head injury, among others (column 3, line 65-column 4, line 10).

Further, Leventer teaches that S-tofisopam can be administered alone or in combination with one or more other anti-convulsant agents to treat convulsions or seizures including myoclonic jerks (i.e., clonic activity) (column 9, lines 45-49).

Leventer does not specifically teach treating dyskinesia per se. Leventer also does not teach that the convulsions or seizures arising from Parkinson’s or Tourette's

syndrome, for example, are a result of dyskinesia associated with dopamine agonist therapy.

As taught by Chenard, dyskinesia is defined as any abnormal or uncontrollable movement including chorea, tremor, dystonia, athetosis, myoclonus and tic (page 10, lines 50-52).

Furthermore, as is well known in the art and also taught by Chenard, dyskinesia is a side effect that results from dopamine agonist therapy in an effort to treat Parkinson's disease (page 2, lines 21-23).

As taught by Chenard, dopamine agonist therapy refers to therapy that increases dopamine receptor stimulation including bromocriptine and increasing levels of dopamine such as L-dopa among others (page 10, line 54-page 11, line 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the administration S-tofisopam for the treatment of convulsions or seizures selected from Parkinson's disease, other neurodegenerative diseases including Huntington's disease, schizophrenia, tics (e.g., Tourette's syndrome) and head injury as taught by Leventer and also used it to treat dyskinesia. As taught by Chenard, dyskinesia is defined as any abnormal or uncontrollable movement including chorea, tremor, dystonia, athetosis, myoclonus and tic. Thus by administering S-tofisopam, one in essence would have been treating the symptoms that arise from the ailments taught by Leventer of which are specific to dyskinesia, a few of which include tics and myoclonic jerks.

Additionally, it would have also been obvious to have administered S-tofisopam for the treatment of dyskinesia as discussed above and also employed the administration of S-tofisopam to treat dyskinesia that arises from an agent that is used to treat Parkinson's disease, namely dopamine agonists. One would be motivated to treat dyskinesia with the administration of S-tofisopam regardless of whether the dyskinesia results from the actual symptoms of a disease, specifically tics arising from Tourette's syndrome, or whether the dyskinesia is a side effect observed upon administration of an agent used to treat a particular disease, namely dopamine agonist therapy for Parkinson's disease.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leventer (US Patent No. 6,649,607 B2) in view of Chenard et al. (EP 0900568 A2) as applied to claims 26-34, 36, 37, 39-45 and 51 above in further view of http://web.archive.org/web/20000815082545/neurologychannel.com/parkinsonsdisease/index.shtml (referred to as "PD website" heretofore).

Leventer and Chenard are discussed above.

Neither Leventer nor Chenard specifically teach the type of parkinsonism (i.e., idiopathic Parkinson's disease).

The "PD website" teaches that the most common type of Parkinson's disease is idiopathic Parkinson's disease because the cause is unknown.

It would have been obvious to one of ordinary skill in the art at the time of the invention that employing the treatment of dyskinesia associated with parkinsonism as

discussed above, that one would have necessarily been treating idiopathic Parkinson's disease. The motivation, provided by the PD website, teaches that idiopathic Parkinson's disease is the most common type of the disease.

Conclusion

Claims 26-37, 39-45 and 50 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627